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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
Liability Litigation

No. MD-15-02641-PHX-DGC

DORIS JONES and ALFRED JONES, a  
married couple,  
Plaintiff,

v.

C.R. BARD, INC., a New Jersey  
corporation and BARD PERIPHERAL  
VASCULAR, an Arizona corporation,

Defendants.

**PLAINTIFF'S BENCH BRIEF  
REGARDING ADMISSIBILITY OF  
MONTHLY MANAGEMENT  
REPORTS & SUMMARY OF  
COMPLAINTS (FRE 1006)**

(Assigned to the Honorable David G.  
Campbell)

1           **A. INTRODUCTION**

2           Plaintiff initiated a meet and confer with Defendants in an effort to pre-admit  
3 exhibits in the interest of judicial economy. Plaintiffs provided Defendants with several  
4 categories of documents including 1) global monthly management reports similar to an  
5 exhibit admitted in the Booker trial (five specific reports were provided), and 2) a  
6 complaint summary chart in compliance with FRE 1006. Plaintiffs previously attached an  
7 almost identical FRE 1006 summary chart consisting of verbatim summaries taken from  
8 Bard's internal complaint records while opposing Bard's Motion *in Limine* No. 1. (Doc.  
9 10068, at fn.1. *See also*, Doc. 10068, at Ex. F).

10           **1. Global Monthly Management Reports**

11           Bard seeks to revisit a ruling from the Booker trial in which the Court admitted  
12 adverse event reports over Bard's hearsay objection based on the foundation provided by  
13 Mr. Modra and based on the *Childs* case (*Booker* Transcript, March 28, 2018, 2302:5-18)  
14 ("I am going to admit the last three pages of document 4327 in light of the *Childs* case and  
15 the testimony of Mr. Modra. It's clear to me that the MDR records that are collected from  
16 representatives and doctors and others are collected regularly in Bard's business, they are  
17 retained in the ordinary course of business. They are relied upon by the company.").

18           Despite Bard's brief urging the Court to reconsider its prior ruling regarding  
19 Defendants' Motion *in Limine* 1, (Doc. 9862)<sup>1</sup> the MDR reports attached to Bard's global  
20 monthly reports are admissible for three independent reasons. First, as the Court  
21 previously ruled, they may be admitted as business records under 803(6), *Childs*, *Kilbride*  
22 and the foundation established by Mr. Modra. Second, the reports are properly admitted  
23 under Rule 801(d)(2)(A), (B), (C), and (D). Not only were the statements made by a party  
24 representative within the scope of employment (facts not contested by Bard), but the  
25 reports are made by Bard's employees under a duty to report. Third, even if not  
26 admissible under the rules cited above, they may be admitted for notice to Bard.

27 \_\_\_\_\_  
28 <sup>1</sup> *See* Doc 10582 (providing an April 10, 2018 deadline to re-urge motions and an April  
18, 2018 deadline to file motions *in limine*).

1 First, the adverse event reports satisfy the business records exception, under  
2 Federal Rule of Civil Procedure 803(6). A record is made in the regular course of business  
3 when it is “made pursuant to established company procedures for the systematic or routine  
4 and timely making and preserving of company records,” and “relied upon by the business  
5 in the performance of its functions. *Clark v. Los Angeles*, 650 F.2d 1033, 1037 (9th Cir.  
6 1981) (citations omitted). “The basis for the business record exception is that accuracy is  
7 assured because the maker of the record relies on the record in the ordinary course of  
8 business activities.” *Id.* See Advisory Committee Note to Rule 803(6). Hearsay  
9 statements are admissible if the observer or participant in furnishing the information to be  
10 recorded was “acting routinely, under a duty of accuracy, with employer reliance on the  
11 result, or in short ‘in the regular course of business.’” *United States v. Pitman*, 475 F.2d  
12 1335 (9th Cir. 1973), cert. denied, 414 U.S. 873, 94 S.Ct. 146, 38 L.Ed.2d 92; Advisory  
13 Committee Note to Rule 803(6).

14 Here, Mr. Modra testified that Bard follows a standard operating procedure for  
15 handling adverse event reports. *Booker Trial Tr.*, March 28, 2018, 2257:22-24.  
16 Complaints are “processed in a uniform and timely manner, investigated, and employees  
17 are responsible for “ensur[ing] that the information received is comprehensive.” Trial Ex.  
18 5691 at 17. Further, the complaints “must be reviewed and determined to be accurate and  
19 complete,” before an investigation is closed. *Id.* at 23. Complaints are investigated to  
20 determine a root cause of a failure, *Id.* at 20, and for “tracking and trending” for safety and  
21 performance. *Booker Trial Tr.*, March 28, 2018, 2259:8-20. Every employee in the  
22 company is trained in complaint handling, and a special department investigates to “get to  
23 the bottom of what happened” when a complaint comes in. *Id.* at 2261:13-2262:15. The  
24 investigation is conducted by quality engineers with engineering degrees to “get as much  
25 information as they can about the event,” and then employees from Research and  
26 Development and Manufacturing are involved during the investigation. *Id.* at 2265:18-  
27 2266:11. In short, the investigation of complaints is comprehensive, governed by FDA  
28 regulation, and supports the accuracy of the statements involved. *Id.* at 2266:21-2269:7.

1 The testimony of a qualified witness (Mr. Modra), 803(6)(D), therefore shows that  
 2 the adverse event reports are “made at or near the time by — or from information  
 3 transmitted by — someone with knowledge,” 803(6)(A), were “kept in the course of a  
 4 regularly conducted activity of a business”, and the recordings were “regular practice of  
 5 that activity,” 803(6)(B), (C), satisfying all elements of 803(6).<sup>2</sup> Bard’s employees were  
 6 additionally under a duty—internal operating procedures and FDA regulations—to report  
 7 the information learned. The evidence here is like the evidence admitted in *Kilbride*,  
 8 where the defendant sought to exclude over half a million complaints sent to various non-  
 9 parties regarding span allegedly sent by the Defendants. *United States v. Kilbride*, No. CR 05-  
 10 870-PHX-DGC, 2007 U.S. Dist. LEXIS 40471, at \*6 (D. Ariz. June 1, 2007) (Campbell, J.).  
 11 The Court held that the complaints were admissible under 803(6) because the  
 12 requirements were met, noting that a “person with knowledge” need not be the one who  
 13 records the information, and this requirement “is liberally construed.” *Id.* at \*7 (quoting 5  
 14 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence*, § 803.08[5]  
 15 (2007)).<sup>3</sup>

16 Second, the reports are statements of an opposing party under Rule 801(d)(2). The  
 17 information is recorded by Bard employees, who are therefore speaking for the party in a  
 18

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19 <sup>2</sup> Reports from third parties fall under 803(6)(A) because they are transmitted by someone  
 20 with knowledge. But in addition, doctors have an independent duty of accuracy in reports  
 21 because they are made pursuant to medical care, so any embedded hearsay is admissible  
 22 for this additional reason. *Clark v. Los Angeles*, 650 F.2d 1033, 1037 (9th Cir. 1981)  
 (embedded hearsay admissible when the reporter “acting routinely, under a duty of  
 accuracy”).

23 <sup>3</sup> The Court relied on *Childs*, which held that information held by dealers in the regular  
 24 course of business was admissible even if the dealers did not make the records at issue, as  
 25 long as “the circumstances indicate the records are trustworthy.” *United States v. Childs*, 5  
 26 F.3d 1328, 1333 (9th Cir. 1993). Contrary to Defendant’s assertion that the underlying  
 27 information was created as a business record, (Brief at 1), the *Childs* court noted only that  
 28 the “documents in question were kept in the regular course of business at the dealerships.”  
*Id.* at 1334 (emphasis supplied). The cases cited by Defendants support Plaintiff’s  
 position, because the evidence here was verified by Bard pursuant to its standard  
 operating procedure.

1 representative capacity. Rule 801(d)(2)(A). Bard has also “manifested that it adopted or  
2 believed to be true,” by investigating and confirming it, and reporting it to the FDA. Rule  
3 801(d)(2)(B); *see Sea-Land Serv. v. Lozen Int’l, LLC*, 285 F.3d 808, 821 (9th Cir. 2002)  
4 (information received and forwarded by employee is adoptive admission); *Metro-*  
5 *Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 454 F.Supp.2d 966, 973 (D. Cal. 2006)  
6 (“If content created by individuals other than the creator of an email is incorporated into  
7 the email, the incorporated content is also admissible non-hearsay under Rule  
8 801(d)(2)(B).”). Finally, statements made by Bard employees are those that are “whom  
9 the party authorized to make a statement on the subject,” and on “matter[s] within the  
10 scope of that relationship and while it existed.” Rule 801(d)(2)(C), (D).

11 Third, the global monthly reports and their summaries of adverse events are  
12 admissible for notice even if not admitted under the above rules. *Drake v. Allergan, Inc.*,  
13 2:13-CV-234, 2014 WL 12717875, at \*2 (D. Vt. Oct. 23, 2014) (“[adverse event reports]  
14 are not hearsay if offered to prove that . . . [Defendant] should have been on notice of the  
15 events alleged in the [reports].”); *Newman ex rel Newman v. McNeil Consumer*  
16 *Healthcare*, 10 C 1541, 2013 WL 4460011, at \*13 (N.D. Ill. March 29, 2013) (adverse  
17 events and rates may be relevant to notice and knowledge). As previously argued, even if  
18 complaints associated with Bard’s IVC filters are considered traditional “other similar  
19 incidents”, analysis from the Ninth Circuit governs this issue. The current state of the law  
20 where a party seeks to introduce other similar incidents to prove up negligence, design  
21 defect, or notice is based on whether those incidents are substantially similar to those  
22 associated with the product at issue. *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d  
23 1103, 1105 (9th Cir. 1991). Where a party seeks admissibility of other incidents for the  
24 purpose of notice, the requirement is “less strict.” *Pau v. Yosemite Park & Curry Co.*, 928  
25 F.2d 880, 889 (9th Cir. 1991). Customer reports, which are essentially what medical  
26 device complaints are, are admissible under the business records exception to the hearsay  
27 rule.  
28

1 This evidence is not cumulative because Bard does not argue that it was unaware of  
2 reports of filter failures. It instead claims there were only a small number of failures.  
3 Evidence of the reports to upper management during the relevant time-period are  
4 probative of the fact that Bard was on notice of more than just one or a small number of  
5 prior failures or lack of effectiveness. Also, Bard assessed and tracked trends in this data,  
6 so any cumulativeness is precisely what is relevant here. Trial Ex. 5691 at 64; *C.f. Cooper*  
7 *v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991) (cumulative prior  
8 accident evidence properly admitted for impeachment purposes because it was “highly  
9 probative of the credibility of the assertion of [Defendant’s] experts that the [product] was  
10 generally safe”). The adverse events are also sufficiently similar to the failures at issue  
11 (e.g., fracture, migration, tilt) in this case because the notice of prior failures in predicate  
12 filters relate to the Eclipse filter. The Eclipse filter was a modification of, and part of the  
13 family, the G2 filter. The G2 filter was a modification of the Recovery and the various  
14 modifications Bard implemented did not address all of the failures that were occurring  
15 then or now. Thus Bard’s notice of tilt, migration, and fracture in prior filters put it on  
16 notice of this issue with the Eclipse filter.

## 17 2. FRE 1006 Summary Chart

18 The same arguments apply to individual complaints Bard received that were  
19 associated with the Eclipse, G2, and Recovery filters. Due to the voluminous nature of  
20 these complaints, Plaintiff seeks to admit a summary of the evidence based on verbatim  
21 reports from Bard’s complaint files. “The admission of summary evidence is within the  
22 discretion of the district court and is upheld absent an abuse of discretion.” *United States*  
23 *v. Bundy*, 2017 WL 549593, at \*1–2 (D. Nev. Feb. 8, 2017) (citing *United States v.*  
24 *Anekwu*, 695 F.3d 967, 981 (9th Cir. 2012). *See also*, *United States v. Marchini*, 797 F.2d  
25 759, 766 (9th Cir. 1986).

26 Charts and summaries may be admitted as evidence under FRE 1006 in lieu of the  
27 underlying records. *United States v. Wood*, 943 F.2d 1048, 1053 (9th Cir. 1991). It’s only  
28

1 when a party seeks to admit the underlying evidence and the summary is the summary not  
2 considered evidence. *Wood*, 943 F.2d 1048, 1053.

3 **B. CONCLUSION**

4 Plaintiff respectfully requests that the Court affirm its ruling in the Booker trial and  
5 admit the MDR reports into evidence.

6 RESPECTFULLY SUBMITTED this 15<sup>th</sup> day of May 2018.

7  
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19 **CERTIFICATE OF SERVICE**

20 I hereby certify that on this 15<sup>th</sup> day of May 2018, I electronically transmitted the  
21 attached document to the Clerk's Office using the CM/ECF System for filing and transmittal  
22 of a Notice of Electronic Filing.

23 /s/ Gay Mennuti